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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,999	11/24/2003	Valentino Montegrando	0424-06	3376

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EXAMINER
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JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/720,999

Applicant(s)

MONTEGRANDE, VALENTINO

Examiner

Jaworski Francis J.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 4-7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11-24-03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

#### **I. Transport Catheter-Delivered Imaging Probe**

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being obvious based upon Taimisto et al (US5351693) as set forth in the prior office action, further in view of Buck et al.

Taimisto et al is directed to a catheter-within-a-catheter system where catheter 10 is a larger transport catheter with an enlarged internal work lumen 36 (Fig.1 and the Fig. 2 cross-section), into which lumen the ultrasound probe 82 shown in Fig. 7 is inserted and thereby delivered to the internal worksite without traumatizing tissue after the transport catheter has been introduced. Therefore:

Taimisto et al teaches an ultrasound imaging system (Note that while the transducer 92 is omni-directional and therefore directionally non-specific insofar as it is cylindrical, an M-mode or echo-line versus time image is none-the-less produced, see col. 12 lines 61 – 69) comprising

an ultrasound probe 82 adapted to be placed in an instrument working channel 36,

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the probe having a probe housing 84 and 140, 142, an ultrasound transducer 92 mounted therein, an elongate flexible cord 96 and/or 98 and its portions described col. 8 line 65 – col. 9 line 35 which extend from the probe housing through the working channel 36 when probe 82 is placed therein, and are adapted to couple to a personal computer, see col. 11 lines 17 – 28.

Hence the argument is made that Taimisto et al anticipates the claimed structure since it is an ultrasound image-producing probe adapted to be passed within a working channel of an internal probe and be connected with a computer, and such a placement adaptation would enable endoscopic placement via a similarly sized working channel. Whereas Taimisto et al does not pertain to a biomarker used in association with an ablation device, it would have been obvious in view of Buck et al (US5803083, newly of record) to provide a marker 17 in association with an ultrasound imager 18 and ablation device 15 since one needs to know the location of a catheter tip during a therapeutic or diagnostic procedure and since Buck et al notes the equivalence of endoscopic and other catheter devices for this purpose, see col.3 bottom..

## **II. Endoscopically Delivered Ultrasound Imaging Probe**

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al, further in view of Buck et al alone or further in view of Ishimura et al (US5255681)..

Martin et al teaches an ultrasound imaging system comprising:

An ultrasound probe 6,8, 190 adapted to be placed in the instrument working channel 5 of an endoscope 2, the probe having a probe housing 194 (Fig. 9

embodiment) within which transducer 190 is mounted, and an elongate flexible cord 202, 204 extending from the housing and through the working channel 5. Since Martin et al feeds an extensive signal processing system of Figs. 18 and 19 by conductor leads 202, 204 inputting to 302,306 of Fig. 18, which leads become multiplied when an array is used, see 235-238 of Fig. 15A, while displacement sensor leads 132, 134, 136 of Fig. 7 feeding to 362 of Fig. 18 are also present, it is argued that such a lead complexity as well as Fig. 18-19 complexity adapts itself to computer control and this adaptability is all that is claim 1 requires since the computer per se is not claimed.

Buck et al is applicable as in the prior rejection.

In the alternative, if Martin et al in view of Buck be argued to fall short of being inherently adapted for use with a computer, it would have been obvious in view of Ishimura et al Figs. 7-9 specifically elements 34 and 41A and col. 11 lines 22 – 29 to use a personal computer to control the synchronizing and data complexity of an ultrasound endoscopic imager using a personal computer because it is cumbersome to design such a system in hardware only.

Hence the Examiner is arguing that the Martin et al endoscopically deliverable ultrasound imaging probe meets all of the claimed structure save for biomarker/ablation adaptability which Buck et al evidences to be per se conventional, or in the alternative the artisan would know to utilize Martin et al with a PC-controlled system since such were used with endoscopic ultrasound imaging probes and therefore would logically extend to use with endoscopically deliverable imaging mini-probes.

### **III. Obvious Extension of Personal Computer-based UTS Imaging**

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Claims 1 –2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiang et al .(US5957846) in view of Martin et al (US4802487), further in view of Buck et al, for reasons set forth in the prior Office action and as supplemented by Buck et al as discussed above.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of the reference combinations applied against claim 1 above, further in view of Takemura (US3927661). While the former are all silent as to inclusion of a galvanometer in an imaging catheter or endoscopically deliverable device, it would have been obvious in view of the latter to use a galvanometer as a scan mechanism to obtain an ultrasound image-producing sweep, the claim 3 providing no further specificity regarding inclusion of a galvanometer.

***Allowable Subject Matter***

Claims 4 – 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to amendment

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Broadest claims remain under rejection since the prior art evidences that biomarkers were well-known to be used to identify catheter or internal probe location particularly where irrevocable effects such as ablation are to be produced.


**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738..

FJJ:fjj

10282004

  
Francis J. Jaworski  
Primary Examiner